TERANG NUSA Sdn Bhd

510(k) Summary
for NUZONE Nitrile Surgical Glove

MAY 2 3 2000

K000178

510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	1 , Jalan 8 Pengkalan Chepa 2 Industrial Zone 16100 Kota Bharu, Kelantan , Malaysia.
Submitter Telephone	+60 9 7735133
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Contact Person	LOW , Chin Guan
Date of preparation	15 Dec 1999
Trade Name	NUZONE
Common Name	Surgical Glove
Classification	Surgeon's Glove
Legally marketed device to which substantial equivalence is being claimed.	The NUZONE nitrile surgical glove described in this 510(k) is substantially equivalent to the Pure Advantage Nitrile Surgical Gloves that is currently marketed.
Description of device	NUZONE meets the requirements for surgical gloves described by the American Standard for Testing and Material ASTM D3577. Type II

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for NUZONE Nitrile Surgical Glove

Intended Use of the device	NUZONE Nitrile surgical gloves are disposable and sterile devices intended to be worn by healthcare personnel to prevent cross contamination between the user and the patient during procedures.
Brief description of non-clinical tests	Test conducted per ASTM D3577, ASTM D512 indicates that the product meet the requirements. Primary Skin Irritation test ASTM F 719-81 and Dermal Sensitization Test ASTM F 720-81 (86) indicates no sensitization or irritation.
Brief description of clinical tests	Not required
Conclusion drawn from clinical and non clinical tests	It can be concluded that NUZONE Nitrile Surgical Gloves will perform according to the performance standards referenced and therefore meets ASTM standards., FDA requirements and labelling claims. This device is substatially equivalent to the currently marketed devices.
Additional information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Mr. Chin-Guan Low
M. Director
Terang NUSA Sdn. Bhd.
1 Jalan 8, Pengkalan Chepa 2 Industrial Zone,
16100 Kota Bharu, Kelantan,
Malaysia

Re: K000178
Trade Name: Nuzone Nitrile Surgical Gloves, Powdered, Green
Regulatory Class: I
Product Code: KGO
Dated: April 18, 2000
Received: April 21 2000

Dear Mr. Low:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for use Statement

Submitter	:	Terang Nusa Sdn Bhd
510(k) Number	:	K 000178
Device Name	:	Nitrile Surgical Glove , Prepowdered, Green
Trade Name	:	NUZONE

Indication for use :

This surgical glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Concurrence of CDHR Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000178

Prescription Use _____ *OR* Over the counter ✓
Per 21 CFR 801.109